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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/935,717 | 09/23/1997 | MICHAEL CATT | IMIN.P-014 | 8965 |

21121 7590 06/18/2003
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EXAMINER

PORTNER, VIRGINIA ALLEN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1645

DATE MAILED: 06/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

08/935,717

Applicant(s)

Catt

Examiner

Portner

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Apr 16, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: the proposed claim amendment raises new issues

3. ☐ Applicant's reply has overcome the following rejection(s): _____
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attachment
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: none
- Claim(s) objected to: 17, 18, 23, 24, and 28-30
- Claim(s) rejected: 11-30
- Claim(s) withdrawn from consideration: _____
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

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The Amendment After-Final submitted April 16, 2003 has not been entered for at least the following reason:

a. The rejection under 35 U.S.C. 112, second paragraph over claim 12 was with respect to what causes the labeled reagent to specifically bind to the detection zone. The issue raised was not a request for the positive recitation of a detection zone location, but for clarification of what in the detection zone caused the labeled reagent to specifically bind thereto, since the only defined structural component of the detection was the porous carrier strip. The proposed amendment of claim 12 to recite “and having the detection zone disposed thereon” does not address the issue raised by the examiner under 35 U.S.C. 112, second paragraph in paper number 22, paragraph 10, pages 9-10.

b. Additionally, the proposed amendment of claim 12 raises a new issue. The new issue being where the detection zone is located. The exact combination of claim limitations which would be in the case if the proposed amendment were entered would be:

“wherein said assay device comprises a porous carrier strip disposed within a hollow casing and having the detection zone disposed thereon,”. The narrative defines the *hollow casing* to be that portion of the device which comprises the porous carrier strip by reciting:

“disposed within” and the phrase following this narrative defines the detection zone to be “disposed thereon”.

The proposed amendment does not add clarity to the claim, by defining the casing or the strip as possible locations for the detection zone. It raises the issue of New Matter as the combination of

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claim limitations (the detection zone disposed on the hollow casing) does not evidence original descriptive support in the instant specification.

c. Entry of the proposed claim amendment would not place the instant Application in better condition for appeal or in condition for allowance.

Response to Remarks

1. With respect to Applicant assertion that the applied prior art does not teach an assay device with a lock and key relationship between the assay strip and an initiating means, it is the position of the examiner that the section of the Office Action, dated January 2, 2003, page 3, paragraph 6, claim 11, primarily addressed the claim limitations directed to an assay device with a detection zone, a reading device and the lock and key relationship between the reading device and the assay device, but at page 4 under the narrative for claim 13, the combination of the lock and key relationship together with initiating means is discussed by citing Catt et al, WO95', claim 13, page 34, which teaches :

a. "Combination"... wherein said receiving means includes actuating means triggered by said receipt of said device, said actuating means causing said reading of said detection zone(s) to be initiated."

Clearly this section defines the inter-relationship of the assay device, the detection zone, and initiation means. The initiation of reading of the detection zone results only upon receipt of the device in the correct lock and key relationship within the receiving means.

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Applicants arguments are essentially the same as those set forth in the prior action. The examiner's responses are herein incorporated by reference to paper number 22, dated January 2, 2003. Catt et al anticipates the instantly claimed invention for reasons of record.

2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

June 12, 2003


LYNETTE R. F. SMITH
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